DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Toyota Tsusho Corporation
% Mr. Doug Blakely
Regulatory Affairs
504 Rittiman Road
SAN ANTONIO TX 78209

November 18, 2014

Re: K131973
Trade/Device Name: UNEXEF-38G Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: September 14, 2014
Received: October 22, 2014

Dear Mr. Blakely:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131973

Device Name
UNEXEF-38G Ultrasound System

Indications for Use *(Describe)*

The system is intended for use by a qualified physician for diagnostic ultrasound imaging or fluid flow analysis of the human body in Peripheral Vascular vessels.
The UNEXEF38G ultrasound instrument is intended to perform the following diagnostic ultrasound investigations: Imaging (A/B-Mode), Color Flow Doppler (CFD), and provides calculations of Flow mediated dilation measurements during reactive hyperemia.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Diagnostic Ultrasound Indications For Use

System: UNEXEF-38G Ultrasound System (K131973)
Transducer: TO-1431

Indications For Use:
The system is intended for use by a qualified physician for diagnostic ultrasound imaging or fluid flow analysis of the human body in Peripheral Vascular vessels.
The UNEXEF38G ultrasound instrument is intended to perform the following diagnostic ultrasound investigations: Imaging (A/B-Mode), Color Flow Doppler (CFD), and provides calculations of Flow mediated dilation measurements during reactive hyperemia.

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B/A	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	YES	YES			YES		
	Other (Specify)							

510(K) Summary

The summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Subpart E, Section 807.92.

The assigned 510(K) number is K131973

Date Prepared: June 24, 2013

1. **Submitters Name, address, telephone number, contact person:**

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San Antonio, TX 78209

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2. **Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

Device Name:
UNEXEF-38G Ultrasound System
Common Name:
Diagnostic Ultrasound system with accessories
Classification:
Regulatory Class II
Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)
21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)
21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. **Identification of the predicate or legally marketed device:**
   Toyota Tsusho Corporation believes the UNEXEF-38G Ultrasound System described in this submission is substantially equivalent to the following devices:
   Fukuda Denshi UF-760AG (K110920)
   Fukuda Denshi UF-870AG (K081919)

4. **Device Description**
   The UNEXEF-38G Ultrasound System is a portable, software controlled ultrasound system used to acquire and display high resolution, real-time ultrasound data in a variety of modes and clinical settings. This system is s Track 3 device that employs an ultrasound probe consisting of ultrasonic transducers arranged in a comb, whereby ultrasound can be generated by supplying electric pulse signals to a group of transducers consisting of multiple adjacent transducers in the single probe.

5. **Intended Use:**
   The system is intended for use by a qualified physician for diagnostic ultrasound imaging or fluid flow analysis of the human body in Peripheral Vascular vessels.
   The UNEXEF38G ultrasound instrument is intended to perform the following diagnostic ultrasound investigations: Imaging (A/B-Mode), Color Flow Doppler (CFD), and provides calculations of Flow mediated dilation measurements during reactive hyperemia.

6. **Safety Consideration:**
   The UNEXEF-38G Ultrasound system has been tested as a Track 3 device per the FDA Guidance document "Information for the Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued in September 2008. The device conforms and has been tested to applicable acoustic output standards as well as medical device safety standards.

Conclusion:

Intended uses and other key features of the UNEXEF-38G are consistent with traditional clinical practice and FDA guidance. The product development process conforms with 21 CFR 820, and ISO 13485 quality systems. The device conforms to applicable electro-medical device safety standards with compliance verified through independent evaluation and on-going internal audits. It is the opinion of Toyota Tsusho Corporation and UNEX that the UNEXEF-38G Ultrasound System is substantially equivalent and is as safe and effective as the legally marketed predicate devices.